IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC.,
800 Scudders Mill Road,
Plainsboro, NJ 08536

NOVO NORDISK PHARMA, INC.,
800 Scudders Mill Road, Suite 1A-108
Plainsboro, NJ 08536

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington D.C. 20201,

ALEX M. AZAR II,
in his official capacity as
Secretary of Health & Human Services
Office of the Secretary
200 Independence Avenue, SW
Washington, D.C. 20201,

ROBERT P. CHARROW,
in his official capacity as
General Counsel of the United States
Department of Health and Human Services,
200 Independence Avenue, S.W.
Washington, D.C. 20201,

HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane,
Rockville, Maryland 20852,

THOMAS J. ENGELS, in his official capacity as Administrator of the Health Resources and Services Administration
5600 Fishers Lane,
Rockville, Maryland 20852,

Defendants.

Civil Action No. 3:21-cv-806

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively, "Novo"), by and through their undersigned attorneys, allege as follows:

PRELIMINARY STATEMENT

1. This case challenges a final decision by the U.S. Department of Health and Human Services ("HHS") that purports to impose new binding obligations on drug manufacturers, on threat of significant penalties, but exceeds the agency's statutory authority and does not comply with the requirements of reasoned decision-making under the Administrative Procedure Act ("APA").

2. Section 340B of the Public Health Service Act requires pharmaceutical manufacturers to offer their outpatient drugs at deeply discounted prices to an enumerated list of "covered entities" for the purpose of ensuring that vulnerable and low-income patients have better access to prescription medications. Manufacturers that fail to comply with the statute's mandate face enforcement action, significant civil monetary penalties, and potential revocation of the manufacturer's ability to participate in the federal Medicare and Medicaid programs.

3. Under the terms of the statute, and consistent with constitutional limits on forcing private parties to subsidize other private parties, Congress provided that *only* covered entities that meet the statute's requirements are entitled to purchase manufacturers' drugs at discounted prices. *See* 42 U.S.C. § 256b(a)(4). Congress also made clear that covered entities are prohibited from transferring manufacturers' drugs to anyone other than their own patients. *See id.* § 256b(a)(5)(B). This prohibition on "diversion" is essential to ensuring that the program remains within constitutional bounds and serves the statutory purpose of aiding needy patients, not enriching covered entities or commercial third parties at manufacturers' expense.

4. Despite these statutory prohibitions, many covered entities have entered into arm's-length agreements with for-profit, commercial pharmacies—known as "contract pharmacies"—that allow the pharmacies to acquire and dispense manufacturers' discounted drugs and to share in the profits resulting from selling manufacturers' discounted drugs at the full market price to patients who are not uninsured or needy. These contractual arrangements have dramatically increased the size of the 340B program, allowing covered entities and their contract pharmacies to make substantial profits at the expense of manufacturers. It has also made it much harder to ensure compliance with the 340B statute, increasing the risk of 340B drugs being sold to non-patients and the problem of "duplicate discounting," which occurs when the same drug is subject to both a 340B discount and a Medicaid rebate. The systemic abuses resulting from this massive expansion in the use of contract pharmacies is directly contrary to Congress's intent.

5. To address these concerns, Novo announced a new initiative, which took effect in January 2021, that it will no longer accept covered entity requests that Novo transfer its covered outpatient drugs (or cause its covered outpatient drugs to be transferred) to an unlimited number of commercial contract pharmacies servicing hospitals. Novo made clear that it will fully comply with the 340B statute by still offering its outpatient drugs at 340B discounted prices to all eligible covered entities. It also made numerous exceptions in its discretion—going beyond what the statute requires—to ensure that federal grantee covered entities are able to purchase Novo's outpatient drugs at the discounted price and dispense them through contract pharmacies. But Novo is no longer willing to allow hospital covered entities and commercial contract pharmacies to abuse the 340B program.

6. Nothing in the statute or any regulation requires manufacturers to facilitate the transfer of their covered outpatient drugs to third parties at a covered entity's request. The statute

requires only that manufacturers "offer" their covered outpatient drugs "for purchase" at discounted prices to eligible "covered entities." 42 U.S.C. § 256b(a)(1). Moreover, although HHS has previously issued guidance permitting covered entities to use contract pharmacies, it repeatedly emphasized that its guidance was non-binding and that the statute itself did not address contract pharmacy arrangements. Under the law, manufacturers have discretion to decide when or whether to honor covered entity requests that their discounted drugs be transferred to third parties, including to for-profit, commercial pharmacies.

7. On December 30, 2021, HHS's Office of General Counsel issued what it labeled an "advisory opinion" but what in fact constitutes a final rule that seeks to change the legal requirements that the 340B program imposes on manufacturers. Without textual support, the agency's decision announces finally and unequivocally that the agency has concluded that drug manufacturers are legally obligated to facilitate the transfer of their discounted drugs to contract pharmacies, which HHS assumed are acting as agents of 340B covered entities. *See* HHS, Office of the Gen. Counsel, *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program* (Dec. 30, 2020) (Ex. A). According to HHS, because the statute requires manufacturers to offer their drugs for purchase at discounted prices, the agency also has authority to require manufacturers to transfer their drugs to wherever covered entities may demand, "be it the lunar surface, low-earth orbit, or a neighborhood pharmacy." HHS Advisory Opinion, Ex. A at 5.

8. HHS's decision is wrong, contrary to the statute, and inconsistent with the requirements of reasoned decision-making. The 340B statute requires manufacturers to "offer" their covered outpatient drugs to covered entities at 340B prices, and Novo's initiative fully complies with that statutory requirement. Nothing in the 340B statute requires manufacturers to facilitate the transfer of their deeply discounted drugs to an unlimited number of contract

pharmacies. Nor does anything in the statute establish that Congress intended to impose such a significant burden on manufacturers or to allow the 340B program to be abused for commercial gain.

9. As a result of HHS's decision, Novo is exposed to enforcement action, severe and accumulating monetary penalties, and potential revocation of its ability to participate in the Medicare and Medicaid programs. Unless and until HHS's decision is struck down, Novo is exposed to the threat of accumulating greater and greater liability.

10. Novo is therefore bringing this action to seek an order (1) declaring that HHS's December 30 decision violates the Administrative Procedure Act because it is in excess of HHS's statutory authority, was issued without following proper procedure, and is not otherwise in accordance with law, (2) declaring that Novo is not required to facilitate the transfer of 340B discounted drugs to contract pharmacies, and (3) enjoining enforcement of HHS's decision and all actions by HHS inconsistent with that declaratory relief.

THE PARTIES

11. Novo Nordisk Inc. is the United States based affiliate of a global healthcare company, founded in 1923, with the purpose to drive change to defeat diabetes and other serious chronic diseases, such as obesity, and rare blood and rare endocrine diseases. Novo Nordisk Inc.'s headquarters are located in Plainsboro, New Jersey.

12. Novo Nordisk Pharma, Inc. supplies unbranded biologic versions of Novo Nordisk insulin products at a reduced list price to individuals facing affordability challenges. Novo Nordisk Pharma, Inc.'s headquarters are located in Plainsboro, New Jersey.

13. Defendant United States Department of Health and Human Services ("HHS") is an executive branch department in the United States government. It is headquartered in the District of Columbia.

14. Defendant Health Resources and Services Administration ("HRSA") is an administrative agency within HHS that is responsible for administering the 340B program. It is headquartered in Rockville, Maryland.

15. Defendant Alex M. Azar II is the Secretary of HHS. His official address is in the District of Columbia. He has ultimate responsibility for overseeing HRSA's activities, including with regard to administering the 340B program. Secretary Azar is sued in his official capacity.

16. Defendant Robert P. Charrow is General Counsel of HHS. His official address is in the District of Columbia. General Counsel Charrow is sued in his official capacity.

17. Defendant Thomas J. Engels is the Administrator of HRSA. His official address is in Rockville, Maryland. Administrator Engels is responsible for administering the 340B program. He is sued in his official capacity.

JURISDICTION AND VENUE

18. Novo brings this action under the Administrative Procedure Act, 5 U.S.C. §§ 701–706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202.

19. The Court has subject matter jurisdiction under 28 U.S.C. § 1331 and 28 U.S.C. § 1361.

20. Defendants' issuance of the December 30 decision constitutes final agency action that is reviewable under the Administrative Procedure Act. *See* 5 U.S.C. §§ 704 - 706.

21. The Court has authority to grant injunctive and declaratory relief and to vacate and set aside the December 30 decision under the Administrative Procedure Act, 5 U.S.C. §§ 701–706, the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, and the Court's inherent equitable powers.

22. Venue is proper in this district under 28 U.S.C. § 1391(e) and 5 U.S.C. § 703 because this action seeks relief against federal agencies and officials acting in their official capacities, Novo resides in this district, and no real property is involved in this action.

GENERAL ALLEGATIONS

A. The 340B Drug Pricing Program

23. This case concerns section 340B of the Public Health Service Act, which created the "340B program" as part of the authority granted in the Veterans Health Care Act of 1992. *See* 42 U.S.C. § 256b; *see also* Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (1992).

24. Before Congress created the 340B program, individual manufacturers helped vulnerable patients by voluntarily providing their drugs at significantly reduced prices to institutions that serve the needy. Turning this voluntary support into a legal mandate, the statute requires that any manufacturer that participates in the Medicaid Drug Rebate Program must "offer" its covered outpatient drugs "for purchase" at deeply discounted prices to eligible "covered entities"—disproportionate share hospitals and other service providers that are expected to serve predominantly low-income and vulnerable patients. 42 U.S.C. § 256b(a)(1).

25. The discounted 340B price is calculated by determining the difference between the manufacturer's Average Manufacturer Price and its Medicaid unit rebate amount, as determined under the Medicaid Drug Rebate Program statute, codified at section 1927 of the Social Security Act. *Id.* § 256b(a)(1)–(2) & (b). The resulting prices, referred to as 340B "ceiling prices," are significantly lower than the prices at which manufacturers sell their products to other purchasers. For the vast majority of innovator drugs, the mandatory discounts range from at least 23.1% to more than 99.9% of the average price in the market. *See* 42 U.S.C. § 1396r-8(c); 42 U.S.C. § 256b(a)(1). Some mandatory 340B ceiling prices are as little as a penny per unit or dose.

26. The purpose of the 340B program is to "reduce pharmaceutical costs for safety-net medical providers and the indigent populations they serve" by creating "a low-cost source of pharmaceutical medication for the indigent patients themselves." Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 Wm. & Mary L. Rev. 637, 638 (2015) (footnote omitted).

27. Although participation in the 340B program is optional, as a practical matter most manufacturers have no choice. If they do not participate in the program, they cannot receive coverage or reimbursement of their products under Medicaid or Medicare Part B. 42 U.S.C. § 1396r-8(a)(1), (5).

28. To indicate their agreement to participate in the 340B program, manufacturers sign a form contract with HHS, referred to as the Pharmaceutical Pricing Agreement. Those agreements are drafted by HHS, they have "no negotiable terms," and they "simply incorporate the statutory obligations and record the manufacturers' agreement to abide by them." *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 117–18 (2011).

29. The Pharmaceutical Pricing Agreement does not impose any obligation on participating manufacturers to sell discounted drugs to contract pharmacies, or to cause their discounted drugs to be transferred to contract pharmacies at 340B discounted prices. The Pharmaceutical Pricing Agreement does not contain the term "contract pharmacy," let alone establish legal obligations on manufacturers with respect to contract pharmacies.

30. Failure to comply with the statutory requirements under the 340B program may result in termination of the Pharmaceutical Pricing Agreement (and the manufacturer's ability to participate in Medicare and Medicaid), as well as enforcement action and potentially the imposition of large civil penalties.

31. Under the 340B statute (and the terms of the Pharmaceutical Pricing Agreement), any manufacturer that participates in the 340B program must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1).

32. Only "covered entities" are eligible to participate in the 340B program, and only "covered entities" and their patients are entitled to receive manufacturers' prescription drugs at the deeply discounted prices that the statute requires.

33. The 340B program does not require covered entities to treat only needy patients with the drugs that manufacturers make available to them at discounted prices, or even (in the case of hospital covered entities) to offer the discounts they receive to needy patients. In short, the discounts that covered entities receive do not have to be, and are typically not, passed on to the patients. Instead, covered entities are permitted to use the 340B drugs to treat any of the patients they serve. By charging the full price of the discounted 340B outpatient drugs to non-needy patients and their insurance companies (and, in the case of hospital covered entities, by charging the full price even to the needy), covered entities are able to obtain significant profits.

34. These profits—the "spread" between the discounted price and the full market price—are not supposed to be used to enrich the covered entities or to benefit other commercial parties. Instead, Congress intended that covered entities would invest the profits to provide care and services to uninsured and underinsured patients.

35. The 340B program raises obvious concerns because the Constitution prohibits the government from forcing the transfer of property at confiscatory prices from one group to another for private benefit. *See* U.S. Const. amend. V. Congress designed the 340B program with the intent that there would be a close nexus between the program and its only valid public purpose

(helping needy patients). Consistent with that intent, the statute is structured to prevent covered entities from using manufacturers' drugs to generate commercial profits or to allow the drugs to be transferred or sold for the financial benefit of entities outside the program.

36. The statute expressly limits which entities—"covered entities"—are entitled to participate in the 340B program and obtain access to 340B covered outpatient drugs at discounted prices. *See* 42 U.S.C. § 256b(a)(4). Consistent with its objective of helping vulnerable and low-income patients gain lower-cost access to life-saving medications, the statute defines "covered entities" to include only organizations that predominantly serve low-income patients. The definition includes, for example, federally qualified health centers, children's hospitals, rural hospitals, and clinics that serve vulnerable patients. *Id*.

37. For-profit third-party pharmacies are not included in the statutory list of "covered entities." *See id*. § 256b(a)(4).

38. The statute expressly forbids "diversion" by prohibiting covered entities from selling or otherwise transferring any manufacturer's discounted drugs "to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity").

39. The statute also prohibits covered entities from receiving or causing "duplicate discounts or rebates," which means that they may not obtain a 340B discount and also cause a Medicaid rebate to be issued for the same unit of drug. *Id*. § 256(a)(5)(A).

40. In addition to these express prohibitions, the statute imposes an affirmative obligation on the Secretary of HHS—authority that has been delegated to HRSA—to protect the program's integrity by "provid[ing] for improvements in compliance by covered entities … in

order to prevent diversion" and violations of the statute's duplicate discount prohibition. *Id.* § 256b(d)(2)(A).

B. The Growth in Contract Pharmacy Arrangements

41. In 1996, HRSA issued non-binding guidance stating that the agency would not prevent covered entities that lacked an in-house pharmacy from entering into a contractual relationship with a single outside pharmacy to dispense covered outpatient drugs to the covered entity's patients. 61 Fed. Reg. 43,549 (Aug. 23, 1996). HRSA justified this modest expansion of the program on grounds that some covered entities lacked in-house pharmacies and any contract pharmacy would function as an "agent" of a covered entity. *See id.* at 43,549–50. The guidance made clear that it "create[d] no new law and create[d] no new rights or duties." *Id.* at 43,550.

42. In 2010, HRSA issued new non-binding guidance that radically changed how covered entities operated under the 340B program. The guidance stated for the first time that the agency would allow covered entities to enter into contractual relationships with an *unlimited* number of "contract pharmacies." 74 Fed. Reg. 10,272 (Mar. 5, 2010).

43. The 2010 guidance did not purport to impose binding obligations on manufacturers. HRSA did not attempt to promulgate a "contract pharmacy rule" through proper notice-and-comment procedures. Instead, as with the 1996 guidance, HRSA made clear that the non-binding guidance did not create any new rights or impose any new obligations. *See id.* at 10,273 ("This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law").

44. Following issuance of the 2010 guidance, covered entities have dramatically increased their use of contract pharmacies, with a recent study reporting an increase of 4,228% between 2010 and today. *See* Aaron Vandervelde et al., *For-Profit Pharmacy Participation in the 340B Program*, at 4 (Oct. 2020) (Ex. B). This explosion in the use of contract pharmacies has

been driven by the prospect of sharing in the outsized profit margins on the deeply discounted 340B drugs.

45. Contract pharmacies, which are predominantly large commercial pharmacy chains, do not operate like in-house pharmacies, do not themselves qualify as covered entities, and do not owe a fiduciary obligation to the covered entities. The relationships between covered entities and the for-profit, commercial pharmacies are governed by arm's-length contracts.

46. Under these arrangements, covered entities direct manufacturers to ship 340B-covered outpatient drugs purchased at the 340B discount to contract pharmacies, which then share in the "spread" generated by selling the drugs at higher prices to patients and/or seeking full commercial reimbursement from the patients' insurance plans. As a result, for-profit pharmacies are able to obtain significant profits from the covered outpatient drugs that manufacturers are required to offer covered entities at deeply discounted prices.

47. By dramatically expanding the pool of individuals that have access to the drugs that covered entities are able to purchase at discounted prices—including individuals who would not otherwise qualify as patients of the covered entity—covered entities are able to obtain profits that extend far beyond Congress's intent when it created the 340B program.

48. One study found that in 2018 alone, covered entities and their contract pharmacies have generated more than $13 billion in estimated gross profits from the purchase of manufacturers' drugs at mandated 340B prices. *See* Vadervelde Report, Ex. B at 7.

49. By bringing commercial pharmacies into the program, there is a significantly greater risk that the covered outpatient drugs will be dispensed to individuals who are not properly classified as "patients" of the covered entity. As HHS has found, contract pharmacy arrangements "create complications in preventing diversion" (for example, contract pharmacies cannot verify

patient eligibility in real-time like a covered entity can). HHS, OEI-05-13-00431, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, at 1 (Feb. 4, 2014) (Ex. C). Indeed, because contract pharmacies often dispense 340B-covered outpatient drugs from the same inventory as drugs dispensed to all other customers (and seek replenishment after the fact), the opportunities for unlawful distributions to ineligible patients increases, allowing covered entities and contract pharmacies to profit from the diversion that Congress intended to prohibit. *See* GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836, at 28 (Sept. 2011) (Ex. D) (noting that "approximately two-thirds of diversion findings in HRSA audits involved drugs distributed at contract pharmacies").

50. Contract pharmacy arrangements also "create complications in preventing duplicate discounts." HHS Report, Ex. C at 2. Because HRSA has only partial insight into which covered entities use which contract pharmacies, and only incomplete information on which covered entities use 340B-discounted drugs for Medicaid-insured patients, there is no effective or comprehensive way to know where a contract pharmacy's prescriptions are being submitted for duplicate discounts—that is, for both a 340B discount (under the covered entity's name) and a Medicaid rebate (under the pharmacy's name).

51. Although covered entities and commercial pharmacies are reaping windfalls as a result of being able to obtain access to manufacturers drugs at discounted prices, uninsured and underinsured patients are not benefitting. *See* HHS Report, Ex. C at 2 (finding that "some covered entities in our study do not offer the discounted 340B price to uninsured patients at their contract pharmacies"); Adam J. Fein, *The Federal Program that Keeps Insulin Prices High*, Wall. St. J. (Sept. 10, 2020) (Ex. E) (explaining that "almost half the U.S. pharmacy industry now profits from

the 340B program, which is designed as a narrow support to certain hospitals," while patients "don't benefit," even though manufacturers have "practically given the product away").

52. In fact, while commercial pharmacies are driving massive growth in the 340B program—at double-digit rates—charity care by hospitals has decreased. Commentators have noted, for example, that while the 340B program has grown at a remarkable rate, the total value of hospitals' uncompensated care has significantly declined. *See* Letter from Adam J. Fein to Hon. Lamar Alexander and Hon. Greg Walden in response to request for input on 340B drug pricing program (Oct. 30, 2020) (Ex. F); Adam J. Fein, *340B Program Purchases Reach $24.2 Billion—7%+ of the Pharma Market—As Hospitals' Charity Care Flatlines*, Drug Channels (May 14, 2019) (Ex. G).

53. HRSA has failed to protect the 340B program's integrity. It has refused to address significant and widespread abuses despite repeated reports and concerns raised by other government entities. *See* GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement,* GAO-18-480 (June 2018) (Ex. H); H. Comm. on Energy & Commerce, *Review of the 340B Drug Pricing Program*, 114th Cong., at 38 (Jan. 11, 2018) (Ex. I); HHS Report, Ex. C.

54. HRSA has also neglected to enforce the statutory prohibitions on diversion, despite serious concerns that commercial contract pharmacies are profiting from the 340B program and that covered outpatient drugs are being unlawfully diverted to individuals who are not patients of the covered entities.

C. Novo's Initiative to Address Contract Pharmacy Abuses

55. Novo and other manufacturers have exercised their lawful right to decline covered entity requests that they cause discounted covered outpatient drugs to be transferred to an unlimited number of commercial pharmacies.

56. Novo has thus implemented a new initiative—which took effect in January 2021—making clear that it will no longer indiscriminately accept covered entity requests that it transfer 340B-covered outpatient drugs to an unlimited number of third-party commercial contract pharmacies servicing hospital covered entities.

57. In implementing this initiative, Novo has confirmed that it will continue to offer "each covered entity" the ability to "purchase" its covered outpatient drugs "at or below the applicable ceiling" price set by statute. 42 U.S.C. § 256b(a)(1).

58. Novo's initiative thus ensures that, as the statute requires, each covered entity is able to purchase Novo's 340B cover outpatient drugs at discounted prices. If a hospital covered entity does not have an on-site pharmacy capable of dispensing to outpatients, Novo will allow the hospital covered entity to designate a single outside contract pharmacy to dispense the product to the covered entity's patients, and Novo will facilitate shipment to that single contract pharmacy.

59. Novo's initiative is tailored to address systemic abuses and, going beyond what the statute requires, includes exceptions for the benefit of covered entities and their patients. Under its new initiative, Novo has made an exception whereby it will facilitate shipment of covered outpatient drugs to an unrestricted number of contract pharmacies that are *wholly owned* by the covered entity. Novo also exempts all federal grantee covered entity types (safety net clinics) from its new initiative, enabling them to continue to use an unlimited number of contract pharmacies.

60. There are no legal requirements—no obligations imposed by any statute or regulation—that require Novo to transfer and ship its drugs to an unlimited number of for-profit commercial pharmacies. Contract pharmacies are not supposed to benefit from the 340B program because they are neither covered entities nor patients.

D. HHS's December 30, 2020 Decision

61. Manufacturers have been transparent with the government about their policies and decisions not to continue honoring covered entity requests to have manufacturers' drugs transferred to third parties.

62. HRSA repeatedly informed manufacturers that agency guidance was not binding or legally enforceable. *See* Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020) (Ex. J).

63. Despite knowing that manufacturers intended to implement policies designed to curb contract pharmacy abuses, HRSA did not identify any statutory provision or other legal requirement that would prevent manufacturers from implementing those policies.

64. Novo alerted HRSA to its intent to adopt its initiative on December 1, 2020.

65. HRSA has never contacted Novo to express any concern over Novo's initiative.

66. In the last two months, covered entities have asked HHS to take enforcement action against manufacturers, including assessing civil monetary penalties, on the view that the statute requires manufacturers to cause their drugs to be transferred to commercial contract pharmacies. They also filed lawsuits seeking to compel HHS to establish a process for adjudicating disputes and to take enforcement action that would require manufacturers to cause their drugs to be transferred to commercial contract pharmacies and pay penalties if they failed to do so. *See Ryan White Clinics for 340B Access et al v. Azar et al*, No. 20-cv-2906 (D.D.C.); *Am. Hosp. Ass'n et al v. HHS et al.*, No. 20-cv-8806 (N.D. Cal.). (Because Novo was referenced in the covered entities' complaint in the case filed in the Northern District of California, it has filed a motion to intervene, and a proposed motion to dismiss the complaint.)

67. In December 2020, the GAO released a report re-affirming that "the 340B statute does not address contract pharmacy use." GAO, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107, at 15–16 (Dec. 2020) (Ex. K).

68. In response to the litigation filed by covered entities, counsel for HHS and HRSA described efforts to compel "participation through contract pharmacies" as improper attempts to foist "wholesale changes to an agency program" on the government. *See* Memo. in Support of Mot. to Dismiss for Lack of Jurisdiction, at 19–20, *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906 (D.D.C. Dec. 14, 2020) (Dkt. 41-1).

69. ***The ADR Rule.*** On December 14, 2020, in a rushed response to the litigation filed by covered entities, HHS promulgated regulations establishing an administrative process for resolving (a) claims by covered entities that they have been overcharged for drugs purchased under the 340B program, and (b) claims by manufacturers, after conducting an audit, that a covered entity has violated the prohibitions on duplicate discounts and diversion. *See id*. § 256b(d)(3)(A). The regulations took effect January 13, 2021. *See 340B Drug Pricing Program; Administrative Dispute Resolution Regulation*, 85 Fed. Reg. 80,632, 80,632 (Dec. 14, 2020) (to be codified at 42 C.F.R. pt. 10) (the "ADR rule").

70. Claims brought under the ADR rule are to be adjudicated by a panel consisting of representatives in equal numbers from the HHS Office of General Counsel, HRSA, and the Centers for Medicare & Medicaid Services ("CMS"). *Id.* at 80,634. The panel is charged with reviewing "[c]laims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." *Id*. § 10.21(c)(1), 85 Fed. Reg. at 80,645.

71. The HHS Office of General Counsel "supervises all legal activities of the Department and its operating agencies," including HRSA and CMS, and furnishes "all legal services and advice to the Secretary, Deputy Secretary, and all offices, branches, or units of the Department in connection with the operations and administration of the Department and its programs." *Statement of Organization, Functions, and Delegations of Authority*, 85 Fed. Reg. 47,228, 47,230 (Aug. 4, 2020).

72. The ADR rule is not a lawful exercise of HHS's authority and does not allow for the fair and unbiased adjudication of claims. HHS failed to respond to serious objections that the ADR process could not work until HHS established a fair and reliable audit process. It failed to address abuses in the program and delegated improper authority to the ADR panels. HHS failed to undertake an adequate notice and comment process. The ADR rule also states that ADR panels will be able to resolve "legal questions," including "whether a pharmacy is part of a 'covered entity.'" 85 Fed. Reg. at 80,633, 80,640.

73. ***HHS's December 30 Decision.*** Two weeks after the publication of the final ADR rule, on December 30, 2020, HHS's General Counsel issued an "Advisory Opinion" asserting that manufacturers are "obligated" to deliver their "covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs" whenever a contract pharmacy acts as a covered entity's "agent." HHS Advisory Opinion, Ex. A at 1.

74. HHS's decision announces the agency's definitive position that manufacturers are prohibited from limiting the transfer of discounted drugs to contract pharmacies, suggesting that "private actor[s]" are not "authorized by section 340B to add requirements to the statute." *Id*. at 2. According to the decision, "[i]f a manufacturer is concerned that a covered entity has engaged

in duplicate discounting or diversion, *see* 42 U.S.C. § 256b(a)(5)(A), (B), it must (1) conduct an audit, and (2) submit the claim to the administrative dispute resolution ("ADR") process, *see id.* § 256b(d)(3)(A)." *Id.* at 5.

75. HHS did not identify any statutory provision that requires manufacturers to cause their discounted drugs to be transferred to commercial contract pharmacies. Its decision's entire textual analysis turns on its unreasoned (and unreasonable) conclusion that because the 340B statute requires manufacturers to "offer" their drugs to covered entities for "purchase" at discounted prices, "[t]he situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant." *Id.* at 3. But that conclusion has no basis in the statutory text. As noted above, the statute requires only that manufacturers "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1).

76. Although the statute expressly prohibits covered entities from selling or transferring covered outpatient drugs to non-patient third parties, HHS assumed that covered entities and contract pharmacies "are not distinct, but function as principal-agent." HHS Advisory Opinion, Ex. A at 6. But HHS did not explain why agency principles are relevant under the statute. It also never explained the basis for its assumption, providing no reason for concluding that a fiduciary obligation exists between covered entities and contract pharmacies or that covered entities have the right to control contract pharmacies—all standard criteria for establishing a principal-agent relationship.

77. HHS also compared transferring drugs to contract pharmacies as akin to using a "courier service" to deliver drugs to patients, but it never explained why that analogy is accurate or appropriate. In particular, it never addressed the reality that contract pharmacies share in the

profits received from the sale of manufacturers' drugs obtained at discounted prices, or that the use of contract pharmacies has caused the 340B program to swell by billions of dollars.

78. HHS's December 30 decision exposes Novo to government enforcement actions for alleged noncompliance, including civil monetary penalties in the amount of $5,000 for *each instance* of noncompliance, *see* 42 U.S.C. § 256b(d)(1)(B)(vi)(II), and the revocation of its ability to participate in Medicare and Medicaid.

79. HHS's decision also subjects Novo to a substantial threat that covered entities will assert claims through the ADR process to challenge Novo's initiative under the terms of HHS's decision—and that ADR panels will rule against and seek to sanction Novo. The ADR panel will consist of representatives from HHS Office of General Counsel, which issued the December 30 decision, and from HRSA and CMS, both of which are HHS agencies subject to the Office of General Counsel's oversight.

80. HHS has made clear that it intends to use the ADR process to impose liability on manufacturers for failing to follow the position taken by HHS in its December 30 decision. Because the December 30 decision conclusively and unequivocally announces HHS's legal position on the contract pharmacy issue, any attempt by a manufacturer to contest the December 30 decision before an ADR panel would be futile. Nothing produced in the administrative record during a specific ADR proceeding would change HHS's legal interpretation.

81. Counsel for covered entities have taken the position that HHS's December 30 decision establishes that the statute requires manufacturers to cause their drugs to be transferred to commercial contract pharmacies. Even though Novo's initiative places *no* limits on the amount of 340B drugs that the covered entity itself is able to purchase at the 340B ceiling price, delivered to the covered entity itself, counsel for the covered entities have threatened that if Novo does not

"immediately discontinue" its initiative, they will "seek to require that HHS enforce the 340B statute, covered entities are reimbursed for damages caused by the [allegedly] illegal policy, and the matter is referred to the HHS Inspector General for the imposition of civil money penalties." Ltr. William B. Shultz to D. Langa, at 2 (Jan. 7, 2021) (Ex. L).

82. Given the threats that have been made by covered entities, it is almost certain that covered entities will file claims against Novo now that the ADR Rule has taken effect. It is also almost certain that, because of its composition and because of HHS's December 30 decision, an ADR panel will treat HHS's December 30 decision as binding in any ADR proceeding and find that Novo's contract-pharmacy initiative violates the statute as interpreted by HHS.

STANDING

83. Novo is injured by HHS's December 30 decision because the decision requires Novo to ship its discounted drugs to contract pharmacies and exposes Novo to enforcement actions and civil penalties that are certainly impending if Novo fails to comply with HHS's new rule.

84. Novo's injuries are fairly traceable to HHS's December 30 decision because it seeks to impose new substantive obligations on drug manufacturers by interpreting the statute as imposing a binding legal requirement that manufacturers must ship their discounted drugs to third parties, such as contract pharmacies, when requested by covered entities. Neither section 340B, nor any existing regulation, nor the Pharmaceutical Pricing Agreement, contains these binding legal requirements.

85. Through its December 30 decision, HHS has taken the position that Novo has no right to limit shipments of its covered outpatient drugs to non-covered entities. As a result of the December 30 decision, Novo is exposed to enforcement actions and accumulating liability and civil monetary penalties, as well as the revocation of its participation in the Medicare and Medicaid

programs, if it fails to comply with the new substantive obligations imposed as a result of the December 30 decision.

86. A favorable ruling is likely to address Novo's injuries. Vacating the December 30 decision and granting declaratory relief would redress Novo's injuries because Novo would not be required to cause its deeply discounted drugs to be shipped to contract pharmacies. Similarly, a declaratory judgment would redress Novo's injuries because Novo would not be exposed to enforcement actions, accumulating liability and civil monetary penalties, or revocation of its participation in Medicare and Medicaid for continuing to limit shipments to third parties that do not qualify as covered entities under the statute.

FINAL AGENCY ACTION

87. The Declaratory Judgment Act provides that, in a case of actual controversy within its jurisdiction, a United States court may declare the rights and other legal relations of any interested party seeking such declaration. 28 U.S.C. § 2201(a).

88. The APA provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702.

89. The APA also provides that "final agency action for which there is no other adequate remedy in a court" is "subject to judicial review." 5 U.S.C. § 704.

90. Although HHS's December 30 decision claims that it "is not final agency action" and "does not have the force or effect of law," the decision is in fact "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. Novo has exhausted all of its available administrative remedies and the pursuit of any further administrative remedies would be futile. Novo does not have any other adequate remedy. *See Army Corps. of Engineers v. Hawkes Co.*, 136 S. Ct. 1807, 1815–16 (2016).

91. HHS's December 30 decision represents the consummation of HHS's decision-making process that drug manufacturers must provide drugs covered under the 340B program to contract pharmacies. HHS reached this decision after years of studying the issues and after reviewing complaints filed by covered entities concerning Novo's and other manufacturers' compliance with the 340B statute. The December 30 decision was issued by HHS's chief legal officer, who has delegated authority to interpret the 340B statute, and the decision is not subject to further review or appeal within HHS.

92. HHS's December 30 decision imposes substantive rights and obligations under the 340B program that do not otherwise exist as a matter of law. Direct and appreciable legal consequences will inevitably flow from the decision if it is not vacated. In particular, if HHS's decision is not enjoined and the statute enforced, Novo will be prevented from exercising its right to limit shipments of its own discounted covered outpatient drugs to non-covered entities. In addition, Novo will be exposed to enforcement actions, potential allegations of overcharging, and accumulating civil monetary penalties, as well as the possible revocation of its participation in the Medicare and Medicaid programs.

93. Novo need not wait for enforcement to occur to challenge HHS's erroneous decision. *See Hawkes*, 136 S. Ct. at 1815; *Pharm. Research & Mfrs. of Am. v. HHS.*, 138 F. Supp. 3d 31, 43 (D.D.C. 2015) (party does not have to wait to file litigation when put to the "painful choice" of either complying with incorrect obligations resulting from agency's statutory interpretation or "risking the possibility of an enforcement action at an uncertain point in the future").

94. Any of these consequences could be devastating to Novo's business and contrary to the public interest. HHS's December 30 decision has put Novo in the untenable position of

either causing deeply discounted drugs to be shipped to ineligible, commercial third parties, or else face crippling financial sanctions for asserting its right to comply with the obligations that are actually in the statute.

95. Any delay in addressing this dispute would be inappropriate because each day that Novo "wait[s] for the agency to drop the hammer," it risks potential "accru[ing]" significant "penalties." *Sackett v. EPA*, 566 U.S. 120, 126–27 (2012). The "direct and immediate" burdens imposed by HHS's December 30 decision mean that the decision warrants immediate judicial review.

96. The need for immediate review is particularly important because, in addition to putting Novo in the untenable position of exercising its rights under the statute or facing severe penalties, HHS's December 30 decision effectuates an unconstitutional taking of property by forcing Novo to transfer its own property (its covered outpatient drugs) to for-profit entities for their private benefit. The Fifth Amendment of the U.S. Constitution forbids this unconstitutional taking, which does not serve any valid public purpose under the 340B statute.

97. Moreover, it is well settled that government may not condition a benefit, such as participating in Medicare Part B and Medicaid, on the relinquishment of a constitutional right. HHS's December 30 decision violates this basic constitutional principle. In order to receive reimbursement and coverage from the federal government—the nation's largest insurance provider—the December 30 decision forces Novo and the rest of the pharmaceutical industry to improperly transfer billions of dollars for the financial benefit of covered entities and large commercial pharmacies, and not the needy patients the 340B program was designed to serve.

CLAIMS FOR RELIEF

COUNT I
(Violation of the Administrative Procedure Act — Contrary to Law and in Excess of Statutory Authority)

98. Novo re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

99. Under the APA, a reviewing court must "hold unlawful and set aside agency action" that is "not in accordance with law" as well as agency action "in excess of statutory … authority." 5 U.S.C. § 706(2)(A), (C).

100. The 340B statute does not confer on HHS (or any of the other defendants) any authority to require drug manufacturers to provide drugs subject to pricing under the 340B statute to contract pharmacies. Contract pharmacies are not covered entities as defined by the 340B statute and the statute does not authorize HHS to require manufacturers to offer discounts to any other type of entity.

101. HHS has no authority to create, through guidance or otherwise, an exception to the statutory prohibition that covered entities may not divert manufacturers' covered outpatient drugs to any entity that is not a patient of the 340B covered entity under the 340B statute.

102. Nor does HHS have any authority to require manufacturers to transfer their deeply discounted covered outpatient drugs to third parties that do not qualify as either covered entities or patients.

103. HHS's December 30 decision is not entitled to *Chevron* or *Skidmore* deference. *See generally Chevron USA, Inc. v. Nat. Res. Def. Council*, 467 U.S. 837 (1984); *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). HHS's decision violates the text of the statute, and Congress has not delegated authority to HHS to expand the 340B program to require manufacturers to facilitate

transferring discounted drugs to third parties, such as contract pharmacies. HHS's position also has no persuasive authority because HHS has not reasonably or rationally explained its position.

104. Because HHS's December 30 decision is contrary to law and in excess of statutory authority, it should be set aside. 5 U.S.C. § 706(2)(A).

COUNT II
(Violation of the Administrative Procedure Act —
Failure to Observe Notice and Comment Procedures Required by Law)

105. Novo re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

106. A court must "hold unlawful and set aside agency action, findings, and conclusions found to be … without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

107. The APA requires agencies to issue rules through a notice-and-comment process. *See* 5 U.S.C. § 553.

108. The APA defines a "rule" as "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4).

109. To issue a valid rule, an agency "shall [ ] publish[]" "[g]eneral notice of proposed rule making" "in the Federal Register," and shall include in that notice "either the terms or substance of the proposed rule or a description of the subjects and issues involved." *Id.* § 553(b). After providing notice of a proposed rule, the agency is required to "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." *Id.* § 553(c).

110. HHS's December 30 decision is a "rule" within the meaning of the APA because it is an agency statement of general applicability to all drug manufacturers, applies prospectively,

and implements, interprets, or prescribes HHS's law or policy with respect to drug manufacturers' obligations under the 340B statute.

111. HHS's decision is not exempt from the APA's notice-and-comment requirements under 5 U.S.C. § 553(b)(A), because it is not an "interpretive rule[], general statement[] of policy, or rule[] of agency organization, procedure, or practice." It is a legislative rule because it creates rights and imposes obligations on manufacturers with which they must comply, on threat of civil sanction and expulsion from the federal Medicaid and Medicare Part B programs.

112. HHS's decision has the force and effect of law because it imposes binding obligations that exceed existing law. Neither the 340B statute nor any regulation requires drug manufactures to provide discounted drugs to contract pharmacies.

113. Novo and other manufacturers are exposed to enforcement actions and civil monetary penalties if they fail to comply with HHS's decision. Noncompliance with HHS's decision also puts at risk manufacturers' participation in Medicare and Medicaid.

114. HHS issued its decision without complying with required notice-and-comment procedures.

115. Because HHS's decision was issued "without observance of procedure required by law," it should be set aside. 5 U.S.C. § 706(2)(D).

COUNT III
(Violation of the Administrative Procedure Act — Arbitrary and Capricious)

116. Novo re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

117. Under the APA, a reviewing court must "hold unlawful and set aside agency action, findings, and conclusions found to be … arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

118. Agency action is arbitrary and capricious if the agency fails to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks omitted). An agency rule is "arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

119. Any change to an agency's policy must be adequately explained. The agency must "display awareness that it *is* changing position," "show that there are good reasons for the new policy," and be aware that longstanding policies may have "engendered serious reliance interests that must be taken into account." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

120. HHS's December 30 decision is arbitrary and capricious because HHS failed to reasonably explain its position or give adequate consideration to the text of the 340B statute, which precludes HHS from imposing an obligation on manufacturers to offer discounts to any entity other than the covered entities Congress specifically enumerated, or to cause its discounted products to be shipped to commercial entities shown to facilitate diversion and duplicate discounting..

121. HHS's decision is arbitrary and capricious because HHS failed to give sufficient or reasoned consideration to the myriad and far-ranging abuses contract pharmacy arrangements have facilitated.

122. HHS's decision is arbitrary and capricious because HHS did not attempt to reconcile the "obligation" imposed by its decision with the agency's earlier pronouncements that

manufacturers were under no legally enforceable obligation to offer 340B prices to contract pharmacies. The December 30 decision fails to explain HHS's dramatic change in policy.

123. HHS's decision is contrary to the requirements of its "good guidance rule." 85 Fed. Reg. 78,770 (Dec. 7, 2020).

124. HHS's decision relies on irrational and illogical reasoning, citing inapt analogies and suggesting that the statute gives HHS authority to force manufacturers to deliver their covered outpatient drugs to any location, even though the statute only requires manufacturers to offer their drugs to covered entities for purchase at the discounted price.

125. Because HHS's December 30 decision is unexplained and irrational, and because it does not consider the relevant factors, it is arbitrary and capricious and should be set aside. 5 U.S.C. § 706(2)(A).

COUNT IV
(Violation of the Administrative Procedure Act —
Contrary to the U.S. Constitution)

126. Novo re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

127. The APA provides that a reviewing court shall "hold unlawful and set aside agency action, … found to be … contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

128. The Takings Clause of the Fifth Amendment provides: "[N]or shall private property be taken for public use, without just compensation." U.S. Const. amend V.

129. The Takings Clause is not limited to instances when government physically appropriates property for its own use through eminent domain. A taking can occur through legislation and regulation that sufficiently deprives a user of its property rights. *See E. Enters. v.*

Apfel, 524 U.S. 498, 529 (1998). The Takings Clause extends to both real and personal property. *Horne v. Dep't of Agric.*, 576 U.S. 350, 358 (2015).

130. HHS's December 30 decision raises substantial constitutional concerns because it imposes a new and unexpected obligations on manufacturers that do not serve any valid public purpose. *See E. Enters.*, 524 U.S. at 528–29.

131. Confiscatory regulations that mandate the transfer of personal property from one private party to another private party amount to an unconstitutional taking with or without just compensation. "[I]t has long been accepted that the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation." *Kelo v. City of New London*, 545 U.S. 469, 477 (2005); *Reagan v. Farmers' Loan & Tr. Co.*, 154 U.S. 362, 399, 410 (1894) (similar). Such private takings are always unconstitutional, since "[n]o amount of compensation can authorize such action." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005); *Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798) ("[i]t is against all reason and justice" to allow government to "take[] property from A. and give[] it to B").

132. In addition, the unconstitutional conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up" to obtain a benefit, such as the ability to participate in a government program. *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013); *see also Libertarian Party of Ind. v. Packard*, 741 F.2d 981, 988 (7th Cir. 1984) ("The 'unconstitutional conditions' doctrine is premised on the notion that what a government cannot compel, it should not be able to coerce."). That includes the rights to retain one's own personal (or business) property unless properly taken by the government. *See Dolan v. City of Tigard*, 512 U.S. 374, 385 (1994); *Nollan v. Cal. Coastal Comm'n*, 483 U.S.

825, 837 (1987). The doctrine "forbid[s] the government from engaging in 'out-and-out … extortion' that would thwart the Fifth Amendment" by coercing private parties, on pain of losing a government benefit, into relinquishing their property without proper compensation. *Koontz*, 570 U.S. at 606 (quoting *Nollan*, 483 U.S. at 837).

133. HHS's decision to mandate that manufacturers transfer their drugs to commercial pharmacies is an impermissibly confiscatory regulation that imposes significant financial losses on Novo and other manufacturers.

134. HHS's decision is also constitutionally suspect because there are no assurances that the transferred property will be used for a public use, as required by the Fifth Amendment. Instead, HHS's decision, if it is not struck down, will force Novo and other manufacturers to transfer their property to other private entities, many (if not most) of which are large commercial pharmacies that use the property for their own private benefit. *Carole Media LLC v. N.J. Transit Corp.*, 550 F.3d 302, 311 (3d Cir. 2008).

135. Moreover, HHS's decision requires this transfer to occur as a condition for participating in Medicaid and Medicare Part B. HHS's decision thus imposes a previously nonexistent condition that directly contravenes the unconstitutional condition doctrine.

136. The broad reading of the 340B statute that is required for HHS's December 30 decision to be within its statutory authority raises serious constitutional concerns. The canon of constitutional avoidance thus weighs heavily against HHS's stained interpretation. *See INS v. St. Cyr*, 533 U.S. 289, 299–300 (2001).

PRAYER FOR RELIEF

WHEREFORE, Novo prays for the following relief

a. A declaration, order, and judgment holding unlawful, enjoining, and setting aside HHS's December 30 decision because it is in excess of HHS's statutory authority,

was issued without following proper procedure, raises significant constitutional concerns, and is arbitrary, capricious, and abuse of discretion, and otherwise not in accordance with law;

b. A declaration, order, and judgment holding that the 340B statute does not require drug manufacturers to transfer or cause their discounted covered outpatient drugs to be transferred to contract pharmacies.

c. A declaration, order, and judgment holding that the 340B statute does not prohibit drug manufacturers from imposing conditions on the provision of covered outpatient drugs at 340B discounted prices to contract pharmacies;

d. A declaration, order, and judgment holding that it is lawful for Novo not to transfer or cause its covered outpatient drugs at 340B discounted prices to be transferred to contract pharmacies;

e. A preliminary and permanent injunction enjoining HHS from enforcing its December 30 decision, including in any administrative proceeding;

f. An award of all costs and attorneys' fees pursuant to any applicable statute or authority; and

g. Any other relief that this Court deems just and proper.

Dated: January 15, 2021

Respectfully submitted,

/s/ Israel Dahan
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